IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

ROY WILMOTH, JR. — PLAINTIFF

v. — CIVIL ACTION NO: 3:20-CV-120-NBB-RP

ALEX M. AZAR, II in his official capacity as Secretary of the United States Department of Health and Human Services — DEFENDANT

WILMOTH'S MEMORANDUM IN SUPPORT OF HIS MOTION FOR SUMMARY JUDGMENT

Plaintiff Roy Wilmoth respectfully submits this memorandum brief in support of his motion for summary judgment. Mr. Wilmoth is entitled to summary judgment because the Secretary is barred by collateral estoppel from denying his claims for Medicare coverage, as a matter of law, and that the coverage denial at issue in this case should be reversed.[1]

This is an administrative review case, the resolution of which turns solely on an issue of law. As detailed in the Complaint and below, Mr. Wilmoth is suffering from a particularly lethal form of brain cancer (glioblastoma multiforme (GBM)).[2] Even with the tumor treatment field therapy (TTFT) that is the subject of the coverage dispute, the two-year survival rate remains well below 50%.

---

[1] Mr. Wilmoth believes that this case could also be decided on the grounds that the Secretary's decision is arbitrary and capricious and not supported by substantial evidence in light of the several decisions finding coverage for Mr. Wilmoth. However, a decision on those grounds would only have effect with regard to Mr. Wilmoth and the particular claim at issue in this case. That is, a decision on any ground other than collateral estoppel will not have broader applicability to either Mr. Wilmoth or the many other people with GBM that are caught in a litigation trap with the Secretary. By contrast, an issued decision on collateral estoppel will benefit Mr. Wilmoth in his future claims as well as other litigants more broadly.

[2] Senator John McCain died in 2018 after a year-long fight with GBM. *See* https://www.curetoday.com/view/john-mccain-dies-of-glioblastoma-at-age-81, last visited (Oct. 30, 2020).

Mr. Wilmoth has repeatedly litigated the issue of whether TTFT is a covered Medicare benefit for him (as well as the sub-issues of, *e.g.*, whether TTFT is "medically reasonable and necessary"/"safe and effective"/not "experimental or investigational"). Mr. Wilmoth has numerous prior and subsequent decisions from ALJs finding in his favor on these issues. The Secretary did not appeal those decisions and they have now become final. Nevertheless, the Secretary continues to force Mr. Wilmoth to re-litigate the identical issues during the time he should be spending with family and focusing on his recovery.

This should stop.

I LEGAL BACKGROUND

Collateral estoppel (*i.e.*, "issue preclusion") is a venerable common law doctrine that bars re-litigation of a legal or fact issue determined in a prior proceeding. Under the doctrine of collateral estoppel, "once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation." *Montana v. United States*, 440 U.S. 147, 153-54 (1979). Collateral estoppel serves the triple purposes of protecting litigants from the burden of relitigating an identical issue against the same party, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *See Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1978).

In the Fifth Circuit, collateral estoppel applies when: 1) the issue at stake is identical to the one involved in the prior action; 2) the issue was actually litigated in the prior action; and 3) the determination of the issue in the prior action was part of the judgment in the earlier action. *See,*

e.g., Southmark Corp. v. Coopers & Lybrand, 163 F.3d 925, 932 (5th Cir. 1999).[3]

As detailed below, Mr. Wilmoth has litigated multiple claims before the Secretary in parallel/concurrently. Parallel/concurrent litigation is common. Where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect on the other. For example, in *Chicago, R.I. & P. RY, Co., v. Elder*, 270 U.S. 611 (1926), the Supreme Court held:

> Nor is it material that the action proceeding, in which the judgment, set up as an estoppel, is rendered, was brought after the commencement of the action or proceeding in which it is pleaded. … Whenever a judgment is rendered in one of the courts and pleaded in the other the effect of that judgment is to be determined by the application of the principles of res judicata by the court in which the action is still pending in the orderly exercise of its jurisdiction, as it would determine any other question of fact or law arising in the progress of the case.

Id. at 615-16.[4] *See also Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922); *Proctor & Gamble Co. v. Amway Corp.*, 376 F.3d 496, 500 (5th Cir. 2004) ("When two suits proceed simultaneously, as in this case, *res judicata* effect is given to the first judgment rendered."); *Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484 (7th Cir. 2015) ("The first to reach final decision can affect the other … through rules of claim and issue preclusion (res judicata and collateral estoppel)[.]"). In other words, a later-filed or decided case that reaches finality first may have preclusive effect on an earlier-filed, but still on-going litigation.

Because of the unique posture of the United States as a litigant, the Supreme Court has held that offensive, non-mutual collateral estoppel does not apply against the United States. *See U.S.*

---

[3] A slightly different formulation of the same elements was presented in *Wehling v. Columbia Broadcasting System*, 721 F.2d 506, 508 (5th Cir. 1983). The showing made below with respect to *Southmark* is equally applicable to the *Wehling*' formulation.

[4] "Res judicata" is a legal doctrine incorporating the concepts of "claim preclusion" (formerly known as "merger" and "bar") and "issue preclusion" (formerly known as "collateral estoppel"). The confusing use of these terms has led to modern efforts to limit "res judicata" to mean "claim preclusion" and to use the term "issue preclusion" instead of "collateral estoppel." *See* THE RESTATEMENT (SECOND) OF JUDGMENTS (1982); *Migra v. Warren City School District Board of Education*, 465 U.S. 75, 77 n. 1 (1984).

v. Mendoza, 464 U.S. 154 (1984). As a result, only a party to a prior proceeding with the government can assert collateral estoppel against the government. Here, Mr. Wilmoth is ***not*** seeking to collaterally estop the Secretary with respect to coverage for TTFT claims filed by any person other than himself. Instead, Mr. Wilmoth only contends that he should not have to re-litigate the same coverage issues against the Secretary that have already been finally and conclusively determined in his favor.[5]

Proceedings giving rise to collateral estoppel are not limited to cases before federal or state courts. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held:

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

(internal citations omitted). *See also B & B Hardware, Inc. v. Hargis Industries, Inc.*, 135 S.Ct. 1293, 1302-3 (2015) (confirming that administrative decisions can be a basis for issue preclusion).

As set forth in *Astoria*, there is a presumption that common law principles (including collateral estoppel) apply to administrative decisions where an agency is acting in a "judicial

[5] Further, Mr. Wilmoth's claim of collateral estoppel is limited to the decision at issue (i.e., coverage for the months of April-June 2018. Whether the Secretary will be estopped on future claims by Mr. Wilmoth will depend on whether Mr. Wilmoth submits them and whether there are "changed circumstances" barring the application of collateral estoppel.

capacity." *Astoria*, 501 U.S at 108 ("where a common-law principle is well established, as are the rules of preclusion, the court may take it is as a given that Congress has legislated with an expectation that the principle will apply except where a statutory purpose to the contrary is evident."). A party asserting that collateral estoppel does not apply bears the burden of establishing the presumption has been overcome. *See Green v. Block Laundry Machine Co.*, 490 U.S. 504, 521 (1989) ("has the burden of showing that the legislature intended such a change.").

In order to overcome the presumption of the common law, the party so asserting must demonstrate that Congress evidenced an intent to do so. *Astoria*, 501 U.S. at 109-110 (common law applies "absent clearly expressed congressional intent to the contrary"); *U.S. v. Texas*, 507 U.S. 529, 535 (1993) ("an expression of legislative intent to supplant"); *Green*, 490 U.S. at 521 (must show "legislature intended such a change").

Moreover, in order to overcome the presumption, a statute must "speak directly" to the common law issue. *See Texas*, 507 U.S. at 534 ("In order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law.", internal citations and quotations omitted). Statutes which are compatible with the pre-existing practice of the common law do not overcome the presumption. *See BFP v. Resolution Trust Corp.*, 511 U.S. 531, 543 (1994).

The application of collateral estoppel based on agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed. App'x. 542 (6th Cir. 2005) (SSA ALJ collaterally estopped by prior ALJ' work determination); *Drummond v. Comm'r of Social Security*, 126 F.3d 837, 841-43 (6th Cir. 1997) (SSA collaterally estopped by prior ALJ work determination); *Continental Can Co., U.S.A., v. Marshall*, 603 F.2d 590 (7th Cir. 1979) (DOL collaterally estopped by prior decisions of department); *Bowen v. United States*, 570

F.2d 1311, 1321-23 (7th Cir. 1978) (NTSB acting in judicial capacity in prior proceeding, plaintiff collaterally estopped); *C & N*, 953 F. Supp. 2d at 912-14 (defendant collaterally estopped by prior TTAB proceeding); *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge's determination). *See also DeWall Enterprises, Inc. v. Thompson*, 206 F. Supp. 2d 992, 1001 (D. Neb. 2002) ("The Secretary's assertions that the ALJ's decisions are not afforded any preclusive effect are without merit.").

II FACTUAL BACKGROUND

A. Tumor Treatment Field Therapy (TTFT)

Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically 3 months. With earlier forms of treatment before TTFT, the survival rate at two years after treatment is ~31%, while at five years, only ~5% of patients are living. Individuals with recurrent GBM have a life expectancy of six months.[6]

More recently, treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates. Indeed, TTFT has proven so effective that, in late 2014, a randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT treatment from the control group.

In ground-breaking papers published in the Journal of the American Medical Association (JAMA)[7] in 2015 and 2017, TTFT was shown to increase the 2-year survival rate by more than

[6] "Recurrent" GBM means that the tumor has increased by 25% since the last treatment.
[7] The Journal of the American Medical Association (JAMA) is widely regarded as one of the most prestigious medical journals in the United States and the world.

38% and to nearly triple the five-year survival rate.[8]

As reported, TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all major private insurers cover TTFT. TTFT extends GBM patients' lives, in some cases, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It has a Level One recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention.[9] Further, TTFT is FDA approved.

The sole supplier of the equipment that delivers TTFT is Novocure, Inc. which manufactures the Optune system. The Optune system is rented on a monthly basis. Once a Medicare patient suffering from GBM is prescribed the Optune system, they will have monthly claims for Medicare coverage. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment will have to continue that treatment for the rest of their lives.

B. The Medicare Appeals Process

People suffering from GBM and being treated with TTFT will have multiple claims for Medicare coverage. Typically, these claims will be submitted every one to three months to reflect their continued usage of the TTFT device. Each claim for Medicare coverage concerns only the one to three months at issue for that claim.

Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5)

---

[8] *See Stupp, et al.*, "MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL", JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); *Stupp, et al.*, "EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA", JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

[9] This is the highest recommendation given to less than 10% of cancer treatments.

level appeal process that can (and typically does) take more than a year. At issue at each stage of the process is whether the claim is a Medicare covered benefit/is medically reasonable and necessary for the beneficiary. The beneficiary begins by submitting a claim. *See* 42 C.F.R. §§ 405.920-928.[10] If the claim is denied, the beneficiary can request "redetermination." *See* 42 C.F.R. §§ 405.940-958. If the claim is still denied, the beneficiary can request "reconsideration." *See* 42 C.F.R. §§ 405.960-978.

If the claim is still denied, the Secretary is required to provide "hearings" for appeals to the "same extent" as is provided for in Social Security hearings. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(b)). That is, in conducting the hearings, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence.

The Secretary has promulgated regulations concerning the conduct of the "hearing" by administrative law judges (ALJs). *See* 42 C.F.R. §§ 405.1000-1058. At a minimum, in the case where the beneficiary is represented by counsel, the hearings are adversarial. In such a case, the Secretary's representative (in the form of the Centers for Medicare and Medicaid Services (CMS) or a "contractor" to Medicare) has the opportunity to litigate as a party. *See* 42 C.F.R. §§ 405.1008 and 405.1010.

In that capacity, the Secretary (like the beneficiary) can submit evidence (42 C.F.R. § 405.1018), object to the timing of the hearing (42 C.F.R. § 405.1020), object to the issues before the ALJ (42 C.F.R. § 405.1024); object to the assigned ALJ (42 C.F.R. § 405.1026); present evidence in the form of documents and witnesses (including through subpoenas), cross-examine witnesses, and present and argument (42 C.F.R. § 405.1036); and take discovery (42 C.F.R. §

[10] At issue in this case are claims submitted under "Original Medicare" (*i.e.*, "Medicare Part B"). Accordingly, the regulatory citations herein are those applicable to Part B claims. Medicare Part C (*i.e.*, "Medicare Advantage Plans") is governed by similar/identical regulations. *See* 42 C.F.R. §§ 422.560-626.

405.1037). After the hearing, the ALJ issues a written decision that includes findings of fact, conclusions of law, and the reasons for the decision and must be based on the evidence admitted at the hearing. *See* 42 C.F.R. § 405.1046.

Like the beneficiary, if the Secretary is dissatisfied with the decision of the ALJ, the Secretary can appeal to the Medicare Appeals Council ("Council"). *See* 42 C.F.R. §§ 405.1100-1140. Indeed, regardless of whether the Secretary chooses to participate in the hearing, the Secretary can appeal an ALJ's decision on so-called "own motion" review. *See* 42 C.F.R. § 405.1110.

Finally, if the beneficiary is dissatisfied with a decision from the Council, they can seek judicial review. *See* 42 U.S.C. § 1395ff(b)(1)(A) (*citing* 42 U.S.C. § 405(g)).

Although the statues and regulations require both ALJs and the Council to issue decisions within 90 days, those deadlines are routinely missed. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2). Thus, Medicare beneficiaries seeking coverage are often thrown into a multi-year effort to obtain coverage or at least get a decision on each denied claim before they can seek relief in a federal court.

C. Mr. Wilmoth

Mr. Wilmoth is a 72-year old retired telephone company employee, father of two (2) and grandfather to five (5). Along with his wife of nearly forty (40) years (Paulette), Mr. Wilmoth lives in Mississippi – just outside of Memphis, Tennessee. In his free time, Mr. Wilmoth enjoys restoring old cars and fishing. Mr. Wilmoth was diagnosed with GBM in February 2016 and, after surgery and chemo-radiation, Mr. Wilmoth began receiving TTFT in May 2017.

1. Figueroa' December 13, 2018 Decision Granting Coverage

Mr. Wilmoth sought Medicare coverage for his TTFT device for the months of September,

October, and November 2017, and his claim was denied initial, denied on redetermination, and denied on reconsideration. Thereafter, through his counsel Parrish Law Office, Mr. Wilmoth requested an ALJ hearing.

On October 30, 2018, ALJ Lissette Figueroa held a hearing at which neither CMS nor a contractor appeared but, *inter alia*, Mr. Wilmoth and his representative (Debra Parrish) did. Thereafter, on December 13, 2018, ALJ Figueroa issued a decision favorable to Mr. Wilmoth in ALJ Appeal No. 1-7835293187. *See* CAR201-212. Among a number of findings supporting TTFT coverage, Judge Figueroa found:

> "The trial shows that the Optune[11] device was safe, non-investigational and effective. And, this trial shows that the Optune device was appropriate for this individual Enrollee's needs, specifically the treatment of newly diagnosed glioblastoma." CAR210;
>
> "Additional material submitted by the Beneficiary also shows the use of TTFT is generally accepted by the medical community." CAR210;
>
> "[F]ind that the Optune device was Medically reasonable and necessary as specifically applied to the Beneficiary's diagnosis and treatment regimen." CAR211;
>
> "After a careful and thorough review of the Appellant's arguments and the evidence in the record, the undersigned ALJ finds the use of the Optune device for an FDA approved indication was expected to and in fact, did make a significantly meaningful contribution to the treatment of Appellant's glioblastoma." CAR211;
>
> "Therefore, the record supports that the claimed Optune device treatment was safe and effective, not experimental or investigational, and appropriate. Accordingly, the device is reasonable and necessary for the treatment of Appellant's glioblastoma." CAR211-212;
>
> "The Appellant's use of the Optune device, HCPCs Code E0766, during dates of service meets requirements for Medicare Part B DME coverage because the device is shown to meet the definition of durable medical equipment, to have been reasonable and necessary for treatment of the Beneficiary's GBM, and to have been for use I the Beneficiary's home." CAR212.

The Secretary did not appeal ALJ Figueroa's decision and it became final no later than December 30, 2018.

[11] "Optune" is the brand name of a TTFT device manufactured by Novocure, Inc.

2. Petrylak' July 2, 2019 Decision Granting Coverage

Mr. Wilmoth sought Medicare coverage for his TTFT device for the months of July, August, and September 2018, and his claim was denied initial, denied on redetermination, and denied on reconsideration. Thereafter, through his counsel Parrish Law Office, Mr. Wilmoth requested an ALJ hearing.

On June 24, 2019, ALJ Joseph Petrylak held a hearing at which neither CMS nor a contractor appeared but Mr. Wilmoth's representative (Debra Parrish) did. Thereafter, on July 2, 2019, ALJ Petrylak issued a decision favorable to Mr. Wilmoth in ALJ Appeal No. 1-8415320334. *See* CAR45-50. Among a number of findings supporting TTFT coverage, Judge Petrylak found:

> "After careful review of the record, the ALJ disagrees with the QIC and finds that there is sufficient documentation to meet the requirement for Medicare payment of the NovoTTF 100-A[12] system and transducer arrays supplies (E0766)." CAR48-49;
>
> "The ALJ after thorough review of this administrative record, find the Appellant has satisfied the Medicare Part B coverage criteria for reimbursement." CAR49;
>
> "I find the documentation and arguments during testimony to be persuasive and demonstrated that the device is not experimental or investigational, but like the FDA, many commercial and Medicaid programs, and recently both the Contractor Advisory Committee and the DAB, I find the device not only to be very effective and useful for its stated uses, but to be the standard of care for glioblastoma treatment." CAR49;
>
> "Accordingly, coverage criteria have been met[.]" CAR49.

The Secretary did not appeal ALJ Petrylak's decision and it became final no later than August 24, 2019.

3. Bryant' May 7, 2019 Decision Denying Coverage

Mr. Wilmoth sought Medicare coverage for his TTFT device for the months of April, May, and June 2018, and his claim was denied initially, denied on redetermination, and denied on

[12] "NovoTTF 100-A" is another name for the Optune TTFT device.

reconsideration. Thereafter, through his counsel Parrish Law Office, Mr. Wilmoth requested an ALJ hearing. *See* CAR195-197. With his request for a hearing, Mr. Wilmoth specifically brought ALJ Figueroa's prior favorable decision to the ALJ's attention.

ALJ Kenneth Bryant was assigned and Mr. Wilmoth filed a pre-hearing brief arguing, *inter alia*, that the Secretary was estopped from denying coverage in light the prior, decision of ALJ Figueroa. *See* CAR178-183. On April 29, 2019, ALJ Bryant held a hearing at which neither CMS nor a contractor appeared but Mr. Wilmoth's representative (Ms. Parrish) appeared.

On May 7, 2019, ALJ Kenneth Bryant issued a decision in Appeal No. 1-8363484331 rejecting Mr. Wilmoth's claims for coverage. *See* CAR19-25. Contrary to the prior decision of ALJ Figueroa, ALJ Bryant held:

> "After reviewing the record and the Appellant's contentions, the undersigned concludes the TTFT (E0766) provided to the Appellant on April 19, 2018, May 19, 2018, and June 19, 2018, is not covered by Medicare." CAR23;
>
> "Based on the foregoing considerations, the Appellant's claim for tumor treatment field therapy ("TTFT") (E0766) provided to the Appellant on April 19, 2018, May 19, 2018, and June 19, 2018, is not sufficiently documents to satisfy the requirements for coverage pursuant to the applicable Medicare coverage criteria. … Accordingly, the item was not medically reasonable and necessary pursuant to § 1862(a)(1)(A) of the Act." CAR25;
>
> "The tumor treatment field therapy ("TTFT") (E0766) provided to the Appellant on April 19, 2018, May 19, 2018, and June 19, 2018, is not medically reasonable and necessary, as required by Section 1862(a)(1)(A) and Section 1833€ of the Act. Therefore, payment may not be made under Part B," CAR25.

Thereafter, Mr. Wilmoth timely appealed ALJ Bryant's decision to the Medicare Appeals Council on June 5, 2019. *See* CAR75-79. As detailed therein, Mr. Wilmoth specifically brought ALJ Figueroa's prior favorable decision to the Council's attention and argued that the Secretary was barred by collateral estoppel from denying coverage (*see* CAR79). Thereafter, on September 18, 2019, Mr. Wilmoth also brought ALJ Petrylak's decision of July 2, 2019 to the Council's attention. *See* CAR37-50.

On October 15, 2019, the Council issued a decision denying Mr. Wilmoth's claim. *See* CAR3-8. Again, contrary to ALJs Figueroa and Petrylak, the Council held that TTFT was not a Medicare covered benefit for Mr. Wilmoth and adopted ALJ Bryant's decision. Specifically, in relevant part, the Council held:

> "For the reasons set forth below, the Council agrees with the ALJ that Medicare does not cover the Optune device. We adopt the ALJ's decision." CAR3.
>
> "We find that the Optune device for delivery of TTFT provided to the beneficiary on a rental basis from April 19, 2018 through June 19, 2019 [sic], is not covered by Medicare Part B." CAR8.

With regard to collateral estoppel, the Council held:

> Finally, the beneficiary argues that the ALJ was estopped from denying coverage based on two prior ALJ rulings finding that Medicare coverage of TTFT provided to the beneficiary on different dates of serve was reasonable and necessary. Exh. MAC-1. However, ALJ decisions do not have precedential effect. 82 Fed.Reg. 4974, 4979 (Jan. 17, 2017). Moreover, it is generally the role of the Council, which like the ALJ conducts a de novo review of the entire administrative record, to issue final decision on behalf of the Secretary. *Id.*; 42 C.F.R. § 405.1108(a). Thus, issue preclusion is not applicable here.

CAR7. Thus, the Council denied Mr. Wilmoth's claim. Thereafter, Mr. Wilmoth timely filed suit in this case.

While Mr. Wilmoth originally filed suit in the District of Columbia, the Secretary objected to venue in his home district and this case was transferred.

4. Other Decisions Granting Coverage

In addition to the decisions of ALJs Figueroa and Petrylak, Mr. Wilmoth also received favorable decisions from ALJs Henningfeld (April 26, 2019); Carolyn Cohn-Morros (October 17, 2019); Carolyn Cohn-Morros (November 14, 2019); Don Joe (February 4, 2020); and Lorenzo Fleming (July 31, 2020). These decisions are collected in **Composite Exhibit "A"**. These decisions cover the time period January-March 2018; October 2018-August 2019.

Each of these decisions follows the same pattern as the decisions of ALJ's Figueroa and

Petrylak. That is, Mr. Wilmoth was represented by counsel (Debra Parrish), the ALJ held a hearing at which neither CMS nor a contractor appeared but Mr. Wilmoth's representative did, the ALJ found that TTFT was a Medicare covered benefit for Mr. Wilmoth (*i.e.*, it was medically reasonable and necessary, safe and effective, etc.), the Secretary did not appeal, and the decision became final 60 days thereafter.

III DISCUSSION

As a result of the separate and final decisions finding TTFT to be a covered benefit/"medically reasonable and necessary" for Mr. Wilmoth, the Secretary is collaterally estopped from issuing denials on the same grounds that were rejected by those other final decisions. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), this Court should reverse the Secretary's denial, order coverage, and remand this case with instructions to the Secretary to effectuate the Court's decision.

A. The Department Was Acting in a Judicial Capacity When It Issued the Prior Decisions

Out of an abundance of caution, Mr. Wilmoth addresses the issue of whether the Department was acting in a "judicial capacity" when it issued the prior decisions and whether the procedures adopted by the Secretary provided the Secretary with a fair opportunity to present his case. There can be little dispute on either point.

As an initial matter, pursuant to the statute, the Secretary is authorized to administer oaths, examine witnesses, and receive evidence in conducting the hearings. *See* 42 U.S.C. § 405(b). The Secretary has further issued regulations confirming the "judicial" and adversarial nature of the hearings and providing the Secretary a fair opportunity to present his case.

As detailed above, at a minimum when the beneficiary is represented, "hearings" before the Secretary are conducted by Administrative Law Judges and the Secretary (through his

representatives) has an opportunity to submit evidence, object to the timing of the hearing, object to the issues at the hearing, object to the assigned ALJ, present evidence in the form of documents and witnesses (including through subpoenas), take discovery, cross-examine witnesses, and present argument. *See* 42 C.F.R. §§ 405.1018, 1020, 1024, 1026, 1036, and 1037. After the hearing, the ALJ issues a written decision including findings of fact and conclusions of law and the reasons for the decision. *See* 42 C.F.R. § 405.1046. Further, if the Secretary is dissatisfied with the ALJ's decision, the Secretary can appeal to the Council using the procedures of 42 C.F.R. §§ 405.1100-1140 (appeal as a party) or 42 C.F.R. § 405.1110 ("own motion review").

Thus, in making the decisions on which estoppel is based, the Secretary (through his administrative law judge) was acting in a judicial capacity and the Secretary had a fair opportunity to present his case.

B. Consideration of Other ALJ Decisions

As noted above, ALJs Henningfeld, Carolyn Cohn-Morros (twice), Don Joe, and Lorenzo Fleming also issued decisions finding coverage for Mr. Wilmoth. While these decisions are not part of the administrative record, this Court may properly take judicial notice of them.

As explained above, because of the nature of collateral estoppel, a later issued decision that becomes final may have preclusive effect on an earlier issued, but non-final, decision. *Chicago*, 270 U.S. at 615-16; *Kline*, 260 U.S. at 230; *Proctor & Gamble*, 376 F.3d at 500; *Adkins*, 779 F.3d at 484.

Thus, independent of their inclusion in the administrative record, this Court may take notice of the "judicial fact" of the subsequent decisions of Cohn-Moros, *e.g.*, regardless of whether they were before the agency at the time the Bryant/Council decisions issued or thereafter. *See Opoka v. INS*, 94 F.3d 392, 394-95 (7th Cir. 1996) ("derelict" in duty to not consider later issued decision).

In the present case, because Mr. Wilmoth believes that the collateral estoppel showing may be made relying solely on the decisions of ALJs Figueroa and Petrylak, he presents a detailed treatment of them herein. That said, each of the other decisions may be used to support the same finding.

C. Collateral Estoppel

Collateral estoppel should conclusively bar the Secretary from re-litigating the issue of TTFT coverage for Mr. Wilmoth.

The Secretary cannot carry his burden of rebutting the presumption that collateral estoppel applies to Medicare cases. No portion of the Medicare statute "speaks directly" to the issue of collateral estoppel or clearly expresses Congress' intent to abrogate the common law. Further, all portions of the statute are compatible with the pre-existing practice of collateral estoppel.

As to the application of collateral estoppel in this particular case, Mr. Wilmoth tracks the elements laid out in *Southmark*. *Southmark*, 163 F.3d at 932.

1. The Issue at Stake Is Identical to the One Involved in the Prior Action

At issue in any Medicare coverage litigation is whether the device/service is a Medicare covered benefit for the beneficiary. This conclusion involves the sub-issues of whether the device/service is "medically reasonable and necessary" for the beneficiary and the further sub-issue of whether the device/service is "safe and effective."[13] *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A) (any item which is not "medically reasonable and necessary" is excluded from coverage). Thus, whenever a coverage decision has determined that a device/service is a Medicare covered benefit, it has necessarily determined that the device/service is medically reasonable and necessary for that particular beneficiary as well as that the device/service is "safe and effective."

[13] Under Medicare's rules, it can never be "medically reasonable and necessary" to provide a device/service that is not "safe and effective."

As noted above, ALJs Figueroa, Petrylak, and the others found that TTFT was a Medicare covered benefit (and the sub-issues of whether it is "medically reasonable and necessary"/"safe and effective") for Mr. Wilmoth. *See, e.g.*, CAR210-12.

Those are the same issues that ALJ Bryant and the Council addressed which the Secretary is collaterally estopped from contesting. Thus, as indicated above, contrary to ALJs Figueroa, Petrylak, and the others, ALJ Bryant and the Council held that TTFT is not "medically reasonable and necessary" and that Medicare coverage does not exist for TTFT. *See* CAR25; CAR3; CAR8.

To the extent that the Secretary alleges that the issues are not identical because each decision covers particular months of treatment, there is no merit to that claim. It is well settled that the test for determining whether facts/issues are identical between two decisions for collateral estoppel purposes is "materiality." That is, facts/issues are identical unless they are materially different with respect to the conclusions reached (*i.e.*, "changed circumstances"). *See, e.g.*, *Montana v. U.S.*, 440 U.S. 147, 159 (1979) ("changes in facts essential to a judgment will render collateral estoppel inapplicable"); *Bernstein v. Bankert*, 733 F.3d 190, 226 (7th Cir. 2013) ("identical in all material aspects"); *Scooper Dooper, Inc., v. Kraftco Corp.*, 494 F.2d 840, 846 (3rd Cir. 1974). There is no material difference regarding coverage between, *e g.*, July 2018 (when ALJ Petrylak found coverage) and, *e.g.*, June 2018 (when ALJ Bryant and the Council held there was no coverage).

The issue at stake in the current appeal is identical to the one in ALJ Figueroa, Petrylak, and the other's decisions.

2. The Issue Was Actually Litigated in the Prior Action

As detailed above, the issue of whether Medicare coverage exists for Mr. Wilmoth's TTFT was actually litigated in the proceedings before ALJs Figueroa, Petrylak, and the others (as well

as the sub-issues of whether the device/service is "medically reasonable and necessary" for the beneficiary and the further sub-issue of whether the device/service is "safe and effective.").

Moreover, unlike a default, Mr. Wilmoth was put to his burden of proof before ALJs Figueroa, Petrylak, and the others. *See, e.g.*, CAR204 ("The burden of proving each element of a Medicare claim lies with the Appellant and is by preponderance of the evidence (i.e., satisfied through the submission of sufficient evidence in accordance with Medicare rules)." - *citing statutes and regulations*). *See Restatement (Second) of Judgments* § 27 cmt. d (1982) ("When an issue is properly raised, by the pleadings or otherwise, and is submitted for determination and is determined, the issue is actually litigated."); *Matter of Garner*, 56 F.3d 677, 680 (5th Cir. 1996) (defendant who answered Complaint but did not otherwise appear, bound by collateral estoppel because plaintiff put to burden of proof).

The issue of whether TTFT is a Medicare covered benefit (and the relevant sub-issues) decided against Mr. Wilmoth by ALJ Bryant and the Council was actually litigated in the prior actions before ALJs Figueroa, Petrylak, and the others.

3. The Determination of the Issue Was Part of the Judgment in the Earlier Action

Of course, the base issue in each Medicare coverage dispute is whether an item/service is a Medicare covered benefit. Thus, the determination on that issue was necessary to the outcome of the proceedings before ALJs Figueroa, Petrylak, and the others (on which collateral estoppel is based) just as it was for the decisions of ALJ Bryant and the Council.

Likewise, because there could be no determination that TTFT was a Medicare covered benefit for Mr. Wilmoth without a determination that TTFT was "medically reasonable and necessary" for him, that determination was part of the final judgments. Likewise, because whether something is "medically reasonable and necessary" is itself dependent on whether it is "safe and

effective", again, that finding was part of the final judgments. Thus, determination of the same issues on which preclusion is sought was part of the judgments by ALJs Figueroa, Petrylak, and the others.

In other cases, the Secretary has asserted that unappealed decisions of ALJs are not "final." There is nothing to this claim. The favorable decisions of ALJs Figueroa, Petrylak and the others are final decisions by ALJs within the jurisdiction of the Secretary's Department itself. *See, e.g.*, CAR204 ("The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council."); 70 Fed.Reg. 36386-7 (June 23, 2005) ("The ALJs within the Office of Medicare Hearings and Appeals issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council[.]"); 42 C.F.R. § 405.1102 ("… a written request for a Council review within 60 calendar days …").

Separate from the Secretary's statements, the decisions of ALJs Figueroa, Petrylak, and the others are also final pursuant to the guidance of the Supreme Court. *See Smith v. Berryhill*, 139 S.Ct. 1765, 1775-76 (2019) (under APA, action is "final" if it: 1) marks the consummation of the agency's decision-making process; and 2) is one by which rights have been determined or from which legal consequences will flow). Given the Secretary's failure to appeal the decisions of ALJs Figueroa, Petrylak, and the others within 60 days, there can be no doubt that those decisions marked the consummation of agency's decision-making process and by which Mr. Wilmoth's rights were determined.

4. The Secretary Had a Fair Opportunity to Litigate the Issue in the Prior Proceedings & Collateral Estoppel is not "Unfair"

While it does not appear that opportunity to litigate or "fairness" are elements of the collateral estoppel in this Circuit, they are present nonetheless and Mr. Wilmoth address them to avoid any counterarguments.

As indicated, Mr. Wilmoth was represented in the cases before ALJs Figueroa, Petrylak, and the others. Thus, pursuant to 42 C.F.R. §§ 405.1008 and 405.1010, the Secretary had the full rights of a litigant to present his case. As this Court knows, in other cases, the Secretary alleged that the sheer volume of ALJ appeals made the application of collateral estoppel "unfair" and/or that the Secretary did not have a fair opportunity to litigate. For example, in *Oxenberg v. Azar*, Case No. 20-cv-738 (E.D. Pa.), the Secretary alleged:

> "It is impracticable for the Secretary to appear as a party in the *over 400,000* Medicare claim appeals that are filed each year at the ALJ level." *See* Dkt. #17 at 2-3 (emphasis in original);
>
> "The Secretary would be forced to devote Medicare resources to actively litigate hundreds of ALJ appeals to avoid the risk of collateral estoppel, thereby taking resources away from tens of millions [sic] Medicare beneficiaries." *See* Dkt. #17 at 3;
>
> "Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate hundreds of thousands of appeals annually." *See* Dkt. #17 at 27.

The Secretary made these same or similar representations in *Christenson v. Azar*, Case No. 20-cv-194 (E.D. Wisc.); *Townsend v. Azar*, Case No. 20-cv-1210 (S.D.N.Y.); and *Piekanski v. Azar*, Case No. 20-cv-687 (M.D. Pa.).

Mr. Wilmoth believes that this is all irrelevant because the Supreme Court affirmed the application of collateral estoppel against the government knowing that the United States was (at that time) a party to ~33% of all litigation in the United States. *See U.S. v. Mendoza*, 464 U.S. 154, 159-60 (1984). Thus, whatever the number of appeals, the Secretary is still subject to collateral estoppel.

Further, as Mr. Wilmoth has pointed out, under the Secretary's own regulations, the total number of appeals is irrelevant because the Secretary may only appear as a party in appeals where the beneficiary is represented. Thus, appeals where the Secretary could not appear add no burden

on the Secretary. However, the Secretary never provided the data on the number of appeals where the beneficiary was represented.

Thereafter, in this case (and in others) the plaintiffs sought discovery on the number of appeals where the beneficiary was represented. The Secretary resisted providing that information, ultimately requiring motion practice in two courts and two hearings. When the Secretary was ordered to provide the information, the reason for the Secretary's intransigence became clear.

On October 27, 2020, the Secretary served interrogatory answers indicating that in FY2019, the number of ALJ appeals filed where the beneficiary was represented (and the Secretary, therefore, was permitted to participate) was 2,602 - nationwide. *See* **Exhibit "B"**. Thus, rather than the Secretary appearing "as a party in over 400,000 Medicare claim appeals that are filed each year at the ALJ level", or the Secretary appearing as a party in the ~44,000 ALJ appeals filed each year, or the Secretary appearing as a party in the ~5,100 beneficiary appeals filed each year, the Secretary could have actually appeared in a maximum of 2,602 represented beneficiary appeals filed at the ALJ level in FY2019. To put that in context, 2,602 is only 0.65% of the 400,000 appeals represented to other courts by the Secretary. To further put that in context, on average that is 50 represented beneficiary appeals filed each week (*i.e.*, one per week from each State in the nation).

Further, the Secretary has published data indicating that in FY2019 more than 54% of the appeals filed were dismissed (*e.g.*, as untimely or due to the death of the beneficiary).[14] Multiplying this dismissal rate by the number of represented beneficiary appeals and subtracting that from the total, results in 1,415 represented beneficiary appeals. That is, in only 1,415 cases an ALJ hearing was presumably held (or the decision issued "on the record") and a decision

[14] *See* https://www.hhs.gov/about/agencies/omha/about/current-workload/decision-statistics/index.html (last visited October 28, 2020).

actually issued. To put that in context, on average that is 27 ALJ hearings per week.[15]

To be clear, these are the maximum number of ALJ hearings the Secretary could appear in, if he so chose. Alternatively, the Secretary could rely on the fact that the beneficiary bears the burden of proof and choose not to attend (as he did in Mr. Wilmoth's cases). As Plaintiffs have pointed out, even in the cases where the Secretary chooses not to appear, the Secretary can appeal a negative decision on so-called "own motion review."

The Secretary had a full and fair opportunity to litigate.

5. Applying Collateral Estoppel is Consistent with the Purposes of the Doctrine

As detailed above, collateral estoppel serves the triple purposes of protecting litigants from the burden of relitigating an identical issue against the same party, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *Allen*, 449 U.S. at 94; *Parklane*, 439 U.S. at 326.

Here, Mr. Wilmoth has seven final decisions holding that TTFT is a Medicare covered benefit for him/medically reasonable and necessary and he has one non-final decision holding the opposite. This is exactly the kind of inconsistent result collateral estoppel exists to preclude. Further, avoiding the wasting of both private party and judicial resources evidenced by the eight (8) written ALJ decisions on the merits, so far, is another basic purpose of collateral estoppel.

D. The Decision at Issue Should Be Reversed and Coverage Ordered

Once this Court properly applies collateral estoppel against the Secretary with respect to the issue of whether TTFT is a covered benefit/is "medically reasonable and necessary" for Mr. Wilmoth, the decision at issue should be reversed. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), this Court can modify or reverse the Secretary's decisions "with or without remanding

[15] *See* the attached Declaration of Debra M. Parrish regarding the volume of ALJ appeals a small law firm can handle, attached as **Exhibit "C"**.

the cause for a rehearing." If the Secretary is collaterally estopped from denying coverage to Mr. Wilmoth in Appeal No. 1-9363484331, then there is no need or reason for further review by the Secretary and coverage should be ordered.

III. CONCLUSION

The Secretary should be collaterally estopped from denying that TTFT is a covered Medicare benefit and "medically reasonable and necessary" for Mr. Wilmoth. Mr. Wilmoth has sustained his burden of proving coverage multiple times and should not be tormented by repeated litigation. The decisions at issue in this case should be reversed and coverage of Mr. Wilmoth's claim ordered.

Dated: October 30, 2020.

Respectfully submitted

/s/ H. Ruston Comley
H. Ruston Comley (MS Bar #102307)
Watkins & Eager PLLC
400 East Capital Street (39201)
Post Office Box 650
Jackson, Mississippi 39205-0650
Telephone: (601) 965-1900
Facsimile: (601) 965-1901
rcomley@watkinseager.com

/s/ James C. Pistorino
James Charles Pistorino (Admitted PHV)
Parrish Law Offices
224 Lexington Drive
Menlo Park, California 94025
Telephone: (650) 400-0043
Facsimile: (412) 561-6253
james@dparrishlaw.com

OF COUNSEL:

Robert R. Baugh
Sirote & Permutt, P.C.
Post Office Box 55727

Birmingham, Alabama 35255-5727
Telephone: (205) 930-5307
Facsimile: (205) 212-3860
rbaugh@sirote.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document electronically, using the CM/ECF system, which will send notification of such filing to all parties of record in the above-captioned matter.

This, the 30th day of October 2020.

/s/ H. Ruston Comley
H. Ruston Comley